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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,236	08/29/2000	Jiangehun Xu	210121.427C18	9536

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EXAMINER	
SOUAYA, JEHANNE E	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/24/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/651,236	Xu et al.
Examiner	**Art Unit**
Jehanne Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 19, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-61 and 63* is/are pending in the application.

4a) Of the above, claim(s) *1-3, 11-15, 17-57, 61, and 63* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *4-10, 16, and 58-60* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Aug 29, 2000* is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5,7,11*

18) ☒ Interview Summary (PTO-413) Paper No(s). *13*

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Please note that the art unit designation for the examiner has changed from 1655 to 1634.

Election/Restriction

1. Applicant's election without traverse of Group I, claims 4-10, 16, and 58-60, SEQ ID NO 107, in Paper No. 9 is acknowledged. Claims 1-3, 11-15, 17-57, 61, and 63 (it is noted that the specification is missing claim 62) have been withdrawn from consideration as being drawn to non elected subject matter. An action on the merits of claims 4-10, 16, and 58-60 follows. Please note, with regard to claim 1, as claim 16 is dependent on polypeptide sequences of claim 1, claim 1 will be considered for purposes of 35 USC 112/first and second paragraph rejections as they apply to claim 16. Applicants should amend claim 16, however, to incorporate the appropriate subject matter of claim 1 and to reflect the election of the specific sequence of SEQ ID NO 107.

Priority

2. Applicant's claim for priority under 35 USC 120 and 35 USC 365© is acknowledged. The claims have been awarded the benefit of the filing date of 2/9/1998 as the subject matter in claims 4-10, 16, and 58-60 of the present application (SEQ ID NO 107) was disclosed in application 09/020,956 filed 2/9/1998. With regard to applicant's claim for priority to applications 08/904,804 filed 8/1/1997, and 09/806,099 filed 2/25/1997, the claims have not been awarded the benefit of either filing date as the subject matter disclosed in the present claims was not taught in either the '956 or the '804 applications.

Drawings

3. New corrected drawings are required in this application because some of the drawings are faded copies and the details of the drawings, such as nucleic acid sequences, polypeptide sequences and figure legends cannot be discerned. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. Upon examination of the application, the examiner could not find evidence that applicants submitted the drawings as informal. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4-10, 16, 58, and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising the sequence of SEQ ID NO 107, a polynucleotide encoding the polypeptide of SEQ ID NO 108, a polynucleotide encoding a fusion protein comprising a polypeptide of SEQ ID NO 108, and vectors and host cells comprising these polynucleotides, does not reasonably provide enablement

for an isolated polynucleotide encoding at least 15 amino acid residues of a prostate specific protein or a variant thereof that differs in one or more substitutions, deletions, additions, and/or insertions such that the ability of the variant to react with antigen specific antisera is not substantially diminished wherein the protein comprises an amino acid sequence that is encoded by a polynucleotide comprising a sequence recited in SEQ ID NO 107, a polynucleotide encoding a variant of a prostate specific protein encoded by SEQ ID NO 107, a polynucleotide comprising a sequence recited in SEQ ID NO 107, a polynucleotide comprising a sequence that hybridizes to a sequence recited in SEQ ID NO 107 under moderately stringent conditions, sequences complementary to such, vectors and host cells comprising such, a polynucleotide encoding a fusion protein comprising an immunogenic portion of a polypeptide of 108, an oligonucleotide comprising 10-40 contiguous nucleotides that hybridize under moderately stringent conditions to a polynucleotide encoding a prostate specific protein wherein the protein comprises an amino acid sequence encoded by a polynucleotide recited in SEQ ID NO 107, and to a kit comprising the oligonucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are broadly drawn to mutants, variants and homologs of the polynucleotide of SEQ ID NO 107 as well as fragments of the polynucleotide of SEQ ID NO 107, from any source, which have not been taught in the specification. The specification teaches the polypeptide of SEQ ID NO 108 as well as the nucleic acid sequence of SEQ ID NO 107, which encodes the

polypeptide of SEQ ID NO 108. The specification teaches that the polynucleotide of SEQ ID NO 107 was over expressed in 60% of prostate tumors, detectable in normal kidney, but not detectable in all other tissues tested, including normal prostate tissue (p. 125, line 16-page 126 line 5). The specification teaches that the polypeptide of SEQ ID NO 108 was expressed in 5 out of 5 prostate carcinoma samples tested. The specification teaches that SEQ ID NO 108 was expressed in some normal tissues, such as kidney liver, and brain but not all. The specification teaches that based on the differential expression of SEQ ID NO 108, it could be useful in the diagnosis of prostate cancer. The specification, however, does not teach the biological function of the polypeptide of SEQ ID NO 108. The specification teaches that polynucleotides of the invention may comprise a native sequence (sentence bridging pages 33 and 34) or may comprise a variant, or a biological or antigenic functional equivalent of such. The specification, however, does not teach or describe any variants with mutant or retained biological activity of the polypeptide of SEQ ID NO 108, nor does the specification teach or describe what regions of SEQ ID NO 108 are antigenic, or immunogenic, let alone variants of such which are also antigenic. Although the specification teaches that cDNA splice variants of P504S were found (SEQ ID NOS 600-605), the specification does not teach the function of any of these splice variants, whether they were over expressed in prostate tumor samples vs normal prostate tissue, or whether the their ability to react with antigen specific antisera was not substantially diminished.

Polynucleotides encompassed by the claims however, include a large number of mutants, variants, and homologs of SEQ ID NOS 107 and 108, as well as biological or antigenic

equivalents resulting from missense, frameshift and truncation mutations, from any source, which have not been taught in either the specification or the art. With regard to sequences "recited in" SEQ ID NO 107, and sequences "complementary" to SEQ ID NO 107, since the specification does not make clear the scope of such language, the claims have been interpreted to encompass a polynucleotide that can have as little as nucleotide sequence in common with either SEQ ID NO 107, as well as an unlimited number of sequences on either side. With regard to a polynucleotide encoding at least 15 amino acid residues of a prostate specific protein wherein the protein comprises an amino acid sequence encoded by a polynucleotide "recited in" SEQ ID NO 107, the claim has been interpreted to encompass a polynucleotide comprising a sequence that encodes as little as 15 amino acids of SEQ ID NO 108 with an unlimited number of sequences on either side. The specification, however, has not taught the activity or sequence of any of the large number of polynucleotides encompassed by the broadly claimed invention. With regard to variants whose ability to react with antigen specific antisera is not substantially diminished, the specification has not taught which portions of the polypeptide of SEQ ID NO 108 are antigenic. With regard to variants of the polynucleotide of SEQ ID NO 107, since the specification does not teach the function or biological activity of the polypeptide of SEQ ID NO 108, nor an assay to measure such, the skilled artisan would not know which modifications to the polypeptide of SEQ ID NO 108 would result in a polypeptide with altered biological activity. With regard to a polynucleotide or oligonucleotide comprising a sequence that hybridizes under moderately stringent conditions to SEQ ID NO 107 or to a sequence recited in SEQ ID NO 107, the

sequences encompass mutants, variants and homologs from any source with either retained or altered biological activity. Since the specification does not teach the activity or function of the polypeptide of SEQ ID NO 108 or how it relates to prostate cancer, the skilled artisan would not be able to determine which molecules encompassed by the broadly claimed invention would have retained or altered biological activity and it would further be unpredictable as to how the skilled artisan could modify the molecule without altering it's biological activity.

A sequence search revealed that SEQ ID NO 107 has 97.1% identity to the cDNA encoding peroxisomal α-methylacyl-CoA racemace which is the enzyme responsible for the conversion of pristanoyl-CoA and C27-bile acyl-CoAs to their (S) stereoisomers (see Ferdinandusse et al, Nature Genetics, vol. 24, 2000, pp 188-191). Ferdinandusse teaches, however, that mutations in this gene are associated with adult onset sensory motor neuropathy, and does not teach any association between this gene and prostate cancer, while the specification, does not teach or suggest the use of the claimed polypeptides with adult onset sensory motor neuropathy, does not teach the function or biological activity of the polypeptide of SEQ ID NO 108 and specifically teaches that no significant homologies were found with SEQ ID NO 107 and the EMBL and GenBank databases (p. 120, lines 15-16). Therefore, based on the lack of guidance from the specification or the art, the skilled artisan would not be able to determine a predicable correlation between variants, mutants, or homologs of the polypeptide of SEQ ID NO 108 and an association to prostate cancer.

A correlation between mutants, variant and homologs encompassed by the claims and a specific biological activity and it's association to prostate cancer is clearly unpredictable in light of the lack of guidance from the specification and the state of the art with regard to the specific biological function of the polypeptide encoded by SEQ ID NO:108. Since the specification does not teach the specific biological function or activity of the polypeptide of SEQ ID NO 108, and neither the specification nor the art teach how the function of the polypeptide is associated to prostate cancer nor how the skilled artisan could modify the polypeptide of SEQ ID NO 108 to obtain a polypeptide with either modified biological function or retained biological or antigenic activity in association with it's differential expression in prostate cancer, the skilled artisan would be required to perform undue experimentation to make or use the biologically active or altered polypeptides encompassed by the broadly claimed invention. To practice the invention as broadly as it is claimed, the skilled artisan would first have to determine the function of the polypeptide of SEQ ID NO 108 and it's association to prostate cancer. The skilled artisan would then have to determine what amino acid residues were associated with the expression of the polypeptide in relation to prostate cancer, and then would have to determine which amino acids could be modified to retain biological function, retain the ability to react with antigen specific antisera, or to result in a protein with altered function. Given that the art teaches that a single amino acid change can alter the function of a biomolecule (see Proudfoot et al, Journal of Biological Chemistry, vol. 271, pp 2599-2603, which teaches that extension of recombinant human RANTES by a single residue [Met-RANTES] at the amino terminus was sufficient to

produce a potent and selective antagonist - see abstract) and that some of these changes are unpredictable, and given that the specification does not teach the function of the polypeptide of SEQ ID NO 108 and it's association to prostate cancer such analyses would require trial and error, thus constituting undue experimentation. It is noted that because the skilled artisan would be required to perform undue experimentation to make and use the polynucleotides of claims 4-8, and 58, undue experimentation would also be required to make or use vectors and host cells comprising the polynucleotides of claims 4-8 or a kit comprising the oligonucleotide of claim 58.

Written Description

6. Claims 4-10, 16, 58 and 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to mutants, variants and homologs of the polynucleotide of SEQ ID NO 107 as well as fragments of the polynucleotide of SEQ ID NO 107, from any source, which have not been taught in the specification. The specification teaches the polypeptide of SEQ ID NO 108 as well as the nucleic acid sequence of SEQ ID NO 107, which encodes the polypeptide of SEQ ID NO 108. The specification teaches that the polynucleotide of SEQ ID NO 107 was over expressed in 60% of prostate tumors, detectable in normal kidney, but not detectable in all other tissues tested, including normal prostate tissue (p. 125, line 16-page 126 line 5). The specification teaches that the polypeptide of SEQ ID NO 108 was expressed in 5 out

of 5 prostate carcinoma samples tested. The specification teaches that SEQ ID NO 108 was expressed in some normal tissues, such as kidney liver, and brain but not all. The specification teaches that based on the differential expression of SEQ ID NO 108, it could be useful in the diagnosis of prostate cancer. The specification, however, does not teach the biological function of the polypeptide of SEQ ID NO 108. The specification teaches that polynucleotides of the invention may comprise a native sequence (sentence bridging pages 33 and 34) or may comprise a variant, or a biological or antigenic functional equivalent of such. The specification, however, does not teach or describe any variants with mutant or retained biological activity of the polypeptide of SEQ ID NO 108, nor does the specification teach or describe what regions of SEQ ID NO 108 are antigenic, or immunogenic, let alone variants of such which are also antigenic. Although the specification teaches that cDNA splice variants of P504S were found (SEQ ID NOS 600-605), the specification does not teach the function of any of these splice variants, whether they were over expressed in prostate tumor samples vs normal prostate tissue, or whether the their ability to react with antigen specific antisera was not substantially diminished.

Polynucleotides encompassed by the claims however, include a large number of mutants, variants, and homologs of SEQ ID NOS 107 and 108, as well as biological or antigenic equivalents resulting from missense, frameshift and truncation mutations, from any source, which have not been taught in either the specification or the art. With regard to sequences "recited in" SEQ ID NO 107, and sequences "complementary" to SEQ ID NO 107, since the specification does not make clear the scope of such language, the claims have been interpreted to

encompass a polynucleotide that can have as little as nucleotide sequence in common with either SEQ ID NO 107, as well as an unlimited number of sequences on either side. With regard to a polynucleotide encoding at least 15 amino acid residues of a prostate specific protein wherein the protein comprises an amino acid sequence encoded by a polynucleotide "recited in" SEQ ID NO 107, the claim has been interpreted to encompass a polynucleotide comprising a sequence that encodes as little as 15 amino acids of SEQ ID NO 108 with an unlimited number of sequences on either side. The specification, however, has not taught the activity or sequence of any of the large number of polynucleotides encompassed by the broadly claimed invention. With regard to variants whose ability to react with antigen specific antisera is not substantially diminished, the specification has not taught which portions of the polypeptide of SEQ ID NO 108 are antigenic. With regard to variants of the polynucleotide of SEQ ID NO 107, since the specification does not teach the function or biological activity of the polypeptide of SEQ ID NO 108, nor an assay to measure such, the skilled artisan would not know which modifications to the polypeptide of SEQ ID NO 108 would result in a polypeptide with altered biological activity. With regard to a polynucleotide or oligonucleotide comprising a sequence that hybridizes under moderately stringent conditions to SEQ ID NO 107 or to a sequence recited in SEQ ID NO 107, the sequences encompass mutants, variants and homologs from any source with either retained or altered biological activity. Since the specification does not teach the activity or function of the polypeptide of SEQ ID NO 108 or how it relates to prostate cancer, the skilled artisan would not be able to determine which molecules encompassed by the broadly claimed invention would have

altered or retained biological or antigenic activity. Since the specification does not teach or describe the activity or function of the polypeptide of SEQ ID NO 108 or how it relates to prostate cancer, or to immunogenic or antigenic regions of SEQ ID NO 108, the disclosed structural feature of the polypeptide of SEQ ID NO 108 and the polynucleotide of SEQ ID NO 107 does represent a substantial portion of the claimed genus of polynucleotides.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of a polynucleotide encoding the polypeptide of SEQ ID NO: 108 and the polynucleotide of SEQ ID NO 107, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Applicant should note that because the polynucleotides and oligonucleotides of claims 4-8, 16, and 58-59 do not meet the written description requirement, vectors and host cells comprising the polynucleotides of claims 4-8 and kits comprising the oligonucleotides of claims 58 and 59 also lack written description. Accordingly, the specification does not provide a written description of the invention of claims 4-10, 16, and 58-60.

Indefinite

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 4-7 and 58-59 are indefinite in the recitation of "recited in" as it is unclear if the term is meant to encompass a polynucleotide comprising the sequence "consisting" of SEQ ID NO 107, or a polynucleotide that comprises a sequence "within" SEQ ID NO 107. The

specification does not define the meaning of this term, and therefore, the metes and bounds of the claim are unclear. Note, the same analysis holds for claim 1 as claim 16 is dependent from claim 1.

B) Claim 4 is indefinite in the recitation of "such that the ability of the variant to react with antigen-specific antisera is not substantially diminished" because it is unclear what level of reactivity with antigen specific antisera the variant's reactivity is being compared to. In other words, the "ability of the variant to react with antigen-specific antisera is not substantially diminished" in comparison to what?

C) The term "the protein" in claim 4 lacks sufficient antecedent basis as it is unclear if "the protein" refers to the "prostate specific protein" recited in line 2 or the "variant" recited in line 2.

D) Claim 5 is indefinite as it is unclear from the recitation whether the variant of the prostate specific protein is also prostate specific.

E) Claim 8 is indefinite in the recitation of "complementary" as it is unclear if the full complement of the polynucleotides of claims 4-7 is intended, or any sequence that is complementary to such. It is noted that if applicants intended the latter, the claim also encompasses a single nucleotide as such constitutes a sequence "complementary" to any of the above polynucleotides. Likewise, claim 4 is indefinite in the recitation of "a complement" as it is unclear if the full complement of the any of the sequences of claim 4 is intended.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 5-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession number U89906 (10/7/1997).

U89906 teaches the mRNA sequence for murine alpha-methylacyl-CoA racemace, which possesses 48.8% sequence identity to SEQ ID NO 107, and is therefore a "variant" of SEQ ID NO 107 since murine alpha-methylacyl-CoA racemace is a homologue of human alpha-methylacyl-CoA racemace and the human polypeptide sequence possesses 97.1% amino acid sequence identity to the polypeptide encoded by SEQ ID NO 107 (SEQ ID NO 108). It is noted that claim 5 is being interpreted to mean that the variant of the prostate specific protein is not necessarily prostate specific. With regard to claim 6, the sequence of U89906 comprises a sequence "recited in" (interpreted to mean "within") SEQ ID NO 107 (nucleotides 440-464 of SEQ ID NO 107 are identical to nucleotides 395-419 of U89906).

11. Claim 59 is rejected under 35 U.S.C. 102(a) as being anticipated by accession number A48221 (3/7/1997).

A48221 teaches a nucleic acid of 767 base pairs. Nucleotides 111 to 159 of A48221 are identical to nucleotides 1573 to 1621 of SEQ ID NO 107, therefore, A48221 teaches an oligonucleotide that comprises 10-40 nucleotides "recited in" (interpreted to mean "within") SEQ ID NO 107.

12. Claims 4, and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796, 12/12/1995).

Claim 4 is drawn to "a complement" of an isolated polynucleotide encoding at least 15 amino acid residues of a prostate specific protein or a variant thereof, wherein the protein comprises an amino acid sequence that is encoded by a polynucleotide comprising a sequence recited in SEQ ID NO 107. Brennan teaches an array of trimers (Fig 1B). The trimer AAA taught by Brennan anticipates claim 4 because the trimer AAA is a complement of SEQ ID NO 107 (it is noted that SEQ ID NO 17 recites a number of regions with three or more contiguous Thymidine nucleotides- for example see nucleotides 298-300). It is unclear whether claim 4 is drawn to the full complement of the polynucleotide or to a sequence that is complementary to the polynucleotide, thus the claim has been interpreted to mean sequences "complementary" to the polynucleotide recited in the claim. With regard to claim 6, the trimer AAA comprises a sequence "recited in" SEQ ID NO 107 (see nucleotides 408-410). With regard to claim 7, the trimer AAA comprises a sequence that hybridizes to the sequence of SEQ ID NO 107 as well as to a sequence "recited in SEQ ID NO 107" (interpreted to mean "within" SEQ ID NO 107).

With regard to claim 8, the trimer AAA is complementary to the sequence of SEQ ID NO 107 at nucleotides 298-300.

13. Claims 7 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number G21632 (5/31/1996).

G21632 teaches a nucleic acid sequence of 412 base pairs. From position 47 to position 185, the sequence of G21632 is almost identical (1 mismatch) to the complement of SEQ ID NO 107 from position 1395 to position 1533. Therefore, G21632 teaches a polynucleotide comprising a sequence that hybridizes to a sequence "recited in" SEQ ID NO 107 (interpreted to mean "within" SEQ ID NO 107) (claim 7). With regard to claim 58, G21632 teaches an oligonucleotide that "comprises" 10 to 40 contiguous nucleotides that hybridize under moderately stringent conditions to SEQ ID NO 107.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 4-6, 9-10 and 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 11-12 of U.S. Patent No. 6,262,245. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the '245 patent is drawn to an isolated DNA molecule comprising the sequence of SEQ ID NO 107. Claims 4-6 and 59 are drawn to polynucleotides and oligonucleotides that encode a prostate specific protein encoded by SEQ ID NO 107. Since the specification does not define a length limitation for the terms "polynucleotide" and "oligonucleotide", the claims are coextensive in scope and claims 4-6 and 59 are encompassed by the recitation of claim 1 of the '245 patent. Further, claims 11-12 of the '245 patent are drawn to a vector and host cell comprising the DNA molecule of claim 1 of the '245 patent, which are coextensive in scope with claims 9-10 of the present application, which are drawn to a vector and host cell comprising any of the polynucleotides of claims 4-6 of the present application.

16. Claims 4-10, and 59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 3-4 of copending Application Nos. 09/895,814, 09/780,669, and 09/759,143. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1, section a of the '814, '669, and '143 applications recites in the alternative "an isolated polynucleotide comprising a sequence provided in SEQ 107", section b recites "complements of the sequence provided in SEQ ID NO 107", and section d recites "sequences that hybridize to a sequence provided in SEQ ID NO 107". It is noted that SEQ ID NO 107 in the instant application is identical to SEQ ID

NO 107 from the '814, '669, and '143 applications. Claims 4-6 and 59 of the instant application are drawn to polynucleotides and oligonucleotides that encode a prostate specific protein encoded by SEQ ID NO 107. Since the specification does not define a length limitation for the terms "polynucleotide" and "oligonucleotide", the claims are coextensive in scope and claims 4-6 and 59 are encompassed by the recitation of claim 1, section a of the '814, '669, and '143 applications. Claim 7 of the instant application is drawn to a polynucleotide that comprises a sequence that hybridizes to a sequence recited in SEQ ID NO 107, which is coextensive in scope with claim 1, section d of the '814, '669, and '143 applications. Claim 8 of the instant application encompasses a polynucleotide sequence that is complementary to a polynucleotide of SEQ ID NO 107, which is coextensive in scope with claim 1, section b of the '814, '669, and '143 applications. Further, claims 3-4 of the '814, '669, and '143 applications are drawn to a vector and host cell comprising the DNA molecule of claim 1 of the '814, '669, and '143 applications, which are coextensive in scope with claims 9-10 of the present application, which are drawn to a vector and host cell comprising any of the polynucleotides of claims 4-8 of the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 4-10, 16, and 58-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-10, 16, and 58-60 of

copending Application Nos. 09/636,215, 09/593,793, 09/605,783, and 09/568,100. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 4-10, 16, and 58-60 of the instant application are drawn to polynucleotides and oligonucleotides of SEQ ID NO 107, vectors and host cells comprising polynucleotides of SEQ ID NO 107, and a polynucleotide encoding a fusion protein comprising a polypeptide encoded by SEQ ID NO 107. Claims 4-10, 16, and 58-60 from the '215, '793, '783, and '100 applications are also drawn, in the alternative, to polynucleotides and oligonucleotides of SEQ ID NO 107, vectors and host cells comprising polynucleotides of SEQ ID NO 107, and a polynucleotide encoding a fusion protein comprising a polypeptide encoded by SEQ ID NO 107, as well as other SEQ ID Nos. SEQ ID NO 107 of the instant application, and SEQ ID NO 107 from the '215, '793, '783, and '100 applications are identical, and therefore, the claims are coextensive in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. No claims are allowable.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
4/18/02